IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA ALEXANDRIA DIVISION

ADVANCED LITHIUM ELECTROCHEMISTRY (CAYMAN) Co. Ltd., and ADVANCED LITHIUM ELECTROCHEMISTRY CO., LTD.,

Declaratory Judgment Plaintiffs,

v.

HYDRO-QUEBEC; CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE; UNIVERSITE DE MONTREAL; and LIFEPO4+C LICENSING AG,

Declaratory Judgment Defendants.

Case No. 1:24-cv-01421-RDA-WBP

<u>DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO</u> <u>DISMISS FOR FAILURE TO STATE A CLAIM</u>

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I. INTRODUCTION

Pursuant to Federal Rule of Civil Procedure 12(b)(6), Defendants Hydro-Quebec, Centre National de la Recherche Scientifique, Universite de Montreal, and LiFePO4+C Licensing AG (collectively, "Defendants") respectfully request that the Court dismiss Plaintiffs' Complaint (Dkt. No. 1) for failure to state a claim upon which relief may be granted and, in accordance with Local Civ. R. 7(F), submit this memorandum in support thereof.

Plaintiffs Advanced Lithium Electrochemistry (Cayman) Co., Ltd. and Advanced Lithium Electrochemistry Co., Ltd.'s (collectively, "Plaintiffs") Complaint premises serious allegations of inequitable conduct before the USPTO on demonstrably false facts that are readily debunked by reference to the publicly available file histories of the challenged and reference patents. In addition to these literally false allegations, Plaintiffs have also failed to plead a legally sufficient claim for inequitable conduct, as (i) none of the information allegedly withheld from the USPTO was actually withheld, (ii) the Complaint fails to identify a specific individual alleged to have committed the inequitable conduct, (iii) the Complaint fails to plead the requisite but-for materiality of the allegedly withheld information, and (iv) the Complaint fails to plead the requisite specific intent to deceive the USPTO. Each of these failures requires dismissal of Plaintiffs' claim.

Plaintiffs' request for declaratory judgment of invalidity of the '318 Patent based on obviousness-type double patenting fares no better. Instead of incorrect and incomplete factual allegations, Plaintiffs have pinned their invalidity argument on a mistaken interpretation of the law. Notably, though Plaintiffs' Complaint cites cases on the issue of obviousness-type double patenting, Plaintiffs failed to bring to the Court's attention the recent precedential authority on the issue from the Federal Circuit, which clarifies that Defendants have no cognizable claim. *Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd.*, 111 F.4th 1358, 1369 (Fed. Cir. 2024) ("Put otherwise, the fact

that the ['318] patent expires later is of no consequence here because it is not a *second*, later expiring patent for the same invention.") (emphasis in original) (internal quotation omitted); *see also In re: Cellect, LLC*, 81 F.4th 1216, 1230 (Fed. Cir. 2023) ("[Patent claims] are entitled to their full term, including the duly granted PTA, unless they are found to be later-filed obvious variations of earlier-filed, commonly owned claims.").

II. STATEMENT OF FACTS

Plaintiffs filed their Complaint against Defendants on August 14, 2024. (Dkt. No. 1). In their Complaint, Plaintiffs seek declaratory judgment that U.S. Patent No. 7,601,318 ("the '318 Patent" or "challenged patent") is (1) invalid due to obviousness-type double patenting¹ over U.S. Patent No. 7,285,260 ("the '260 Patent" or "purported reference patent") and (2) unenforceable due to alleged inequitable conduct. (Dkt. No. 1 ¶¶ 18-30).

The '318 Patent issued from Application No. 10/362,763 (the "'763 Application"), which was filed on February 26, 2003 and claimed priority to a PCT application, No. PCT/CA01/01319 filed on September 21, 2001, and is assigned to Defendants Hydro-Quebec, Centre National de la Recherche Scientifique, and Universite de Montreal. The '318 Patent received a congressionally guaranteed patent term adjustment ("PTA") of 1,227 days under 35 U.S.C. § 154(b) due to United States Patent and Trademark Office ("USPTO") delays.

¹ The Count I of the Complaint ("Declaratory Judgment of Invalidity of the '318 Patent") includes a reference in the final paragraph to also seeking "declaratory judgment that the claims of the '318 patent are . . . <u>unenforceable</u> under the [OTDP] doctrine." (Dkt. No. 1 ¶ 24 (emphasis added)). However, a judgment of unenforceability is not available upon a finding of OTDP and there is no plausible factual allegation regarding unenforceability under Count I. Count II seeks "Declaratory Judgment of Unenforceability for Inequitable Conduct." (Dkt. No. 1 ¶¶ 25-31). For the reasons discussed herein, Plaintiffs have failed to sufficiently plead anywhere in their Complaint a case for declaratory judgment of the unenforceability of the '318 Patent.

The '260 Patent issued from Application No. 10/362,764 (the "'764 Application"), which was filed after the '763 Application on the same date of February 26, 2003, and claimed priority to a PCT application, No. PCT/CA01/01350 filed on the same filing date as the PCT application identified by the '318 Patent—September 21, 2001, and is assigned to Defendants Hydro-Quebec, Centre National de la Recherche Scientifique, and Universite de Montreal. The '260 Patent received a PTA of 218 days under 35 U.S.C. § 154(b) due to USPTO delays.

III. STANDARD OF REVIEW

The Court may dismiss a complaint that fails to state a claim upon which relief can be granted under Rule 12(b)(6). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). This plausibility standard requires "more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678.

All well-pleaded allegations in the plaintiff's complaint are accepted as true for the purposes of the motion to dismiss inquiry. *Edwards v. City of Goldsboro*, 178 F.3d 231, 244 (4th Cir. 1999). However, a court is not required to accept any legal conclusions as true. *Iqbal*, 556 U.S. at 678. Instead, "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* at 679. Furthermore, in assessing a Rule 12(b)(6) motion, courts are not confined to the four corners of the complaint and can take judicial notice of matters of public record, such as the file histories of the challenged patent and purported reference patent, as well as certain documents attached to the motion to dismiss that are integral to the complaint and authentic. *See U.S. ex rel. Oberg v. Pennsylvania Higher Educ. Assistance Agency*, 745 F.3d 131, 136 (4th Cir. 2014) ("It is well established that we may properly take judicial notice of matters of public record,

including statutes. We may also consider documents incorporated into the complaint by reference, as well as those attached to the motion to dismiss, so long as they are integral to the complaint and authentic.") (internal quotations and citations omitted).

Generally, to state a claim for which relief can be granted, a complaint must contain at least "a short and plain statement of the claim." FED. R. CIV. P. 8(a)(2). Although the complaint may be short, the statement "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. The complaint must have enough information to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Id.* (ellipses in original) (internal quotation omitted). The pleading standard of Rule 8 "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 678.

"Inequitable conduct, while a broader concept than fraud, must be pled with particularity under Rule 9(b)." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009) (internal quotation omitted). "In sum, to plead the 'circumstances' of inequitable conduct with the requisite 'particularity' under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Id.* at 1328. Under the heightened standard for pleading inequitable conduct under Rule 9(b), the pleading "must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." *Id.* at 1328–29.

IV. ARGUMENT

The Complaint not only fails to provide sufficient facts for the court to "infer more than the mere possibility of misconduct," *Iqbal*, 556 U.S. at 679, but it relies on demonstrably false facts and incorrect law. Specifically, the factual allegations underpinning Plaintiffs' inequitable conduct claim ("Count II") are literally false as evidenced by the public record and Plaintiffs' allegations are insufficient to state a claim for inequitable conduct as a matter of law. Similarly, Plaintiffs' claim for patent invalidity based on obviousness-type double patenting ("OTDP" or "ODP") ("Count I") notably ignores the most recent Federal Circuit precedent on the issue and is insufficient as a matter of law. As such, each of Plaintiffs' requests for declaratory judgment should be dismissed.

A. Count II of the Complaint Should Be Dismissed Because the Allegations Fail to State a Claim for Inequitable Conduct

"Inequitable conduct . . . must be pled with particularity under Rule 9(b)." *Exergen Corp.*, 575 F.3d at 1326 (internal quotation omitted). To state a claim for inequitable conduct—the "atomic bomb of patent law"—Plaintiffs must plead with particularity that the applicants acted "with the specific intent to deceive the PTO" by deliberating misrepresenting or withholding "material information." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287–90 (Fed. Cir. 2011). "Intent and materiality are separate requirements." *Therasense*, 649 F.3d at 1290.

Importantly, the Federal Circuit—in response to the fact that "low standards for intent and materiality ha[d] inadvertently led to many unintended consequences, among them, increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, increased PTO backlog, and impaired patent quality"—"tighten[ed] the standards for finding both intent and materiality." *Therasense*, 649 F.3d at 1289–90. The Federal Circuit's express purpose in doing so was to "reduce the number of inequitable conduct cases before the

courts" to cure the "absolute plague" of such cases "cluttering up the patent system." *Therasense*, 649 F.3d at 1289 (quoting *Kimberly–Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1454 (Fed. Cir. 1984); *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988)). As a result, "[a] charge of inequitable conduct based on a failure to disclose will survive a motion to dismiss only if the plaintiff's complaint recites facts from which the court may reasonably infer that a specific individual both knew of invalidating information that was withheld from the PTO and withheld that information with a specific intent to deceive the PTO." *Delano Farms Co. v. California Table Grape Comm'n*, 655 F.3d 1337, 1350 (Fed. Cir. 2011).

The inequitable conduct claim that Plaintiffs bring is exactly the type of claim "brought on the slenderest grounds" that the Federal Circuit has sought to preclude. *Therasense*, 649 F.3d at 1289. Worse still, it is premised on demonstrably false allegations.

1. Plaintiffs' Claim for Inequitable Conduct Relies on False Allegations

Plaintiffs' inequitable conduct claim relies on purported improper actions taken by the applicants of the '318 Patent during prosecution. In total, Plaintiffs provide the following three paragraphs of allegations in support of their inequitable conduct claim:

- 28. On information and belief, the patent applicant and the attorneys and agents operating on their behalf in submitting the application leading to the '318 patent were aware of the filing of the patent application leading to the '260 patent, which application was filed on the same day. On information and belief, the patent applicant and the attorneys and agents operating on their behalf were aware of the substantial similarity of the subject matter described and claimed in the two patent applications throughout patent prosecution of the two patent families.
- 29. On information and belief, the patent applicants and the attorneys and agents operating on their behalf were aware that the two patent applications were before different patent examiners, and that the patent examiners may not have been aware of the copending patent applications on related subject matter. On information and belief, the patent applicants and the attorneys and agents operating on their behalf did not disclose the existence of the copending patent applications and made a

deliberate decision to withhold information relating to the copending patent applications.

30. On information and belief, the existence of the copending patent applications was material to patentability, because had the patent examiners been aware of the copending patent applications, they would have issued an obviousness-type double patenting rejection and required the filing of a terminal disclaimer, such that the '318 patent would have expired at the same time as the '260 patent. On information and belief, by not disclosing the existence of the copending applications to the patent examiners, the patent applicants have obtained an improper time-wise extension of patent rights by obtaining a second patent (the '318 patent) having claims that are not patentably distinct from an earlier patent.

(Dkt. No. 1 ¶¶ 28-30).

The difficulty for Plaintiffs is that the proceedings between the applicants and the USPTO are recorded in the patent's file history and, as such, are in the public record. A simple review of the file histories of the '318 Patent and the '260 Patent shows that Plaintiffs' allegations are literally false.

For instance, Plaintiffs' Complaint states that the applicants did not disclose the copending applications:

On information and belief, the patent applicants and the attorneys and agents operating on their behalf <u>did not disclose the existence of the copending patent</u> <u>applications</u> and made a deliberate decision to withhold information relating to the copending patent applications. (Dkt. No. 1 ¶ 29 (emphasis added)).

On information and belief, by not disclosing the existence of the copending applications to the patent examiners, the patent applicants have obtained an improper time-wise extension of patent rights by obtaining a second patent (the '318 patent) having claims that are not patentably distinct from an earlier patent.). (Dkt. No. 1 ¶ 30 (emphasis added)).

However, the file histories unequivocally show that the applicants <u>did disclose</u> the copending applications to the examiners. For instance, in a Second² Information Disclosure

² As the applications were filed on the same day, it was not possible for the applicants to disclose the other application number in the initial Information Disclosure Statement submitted at filing.

Statement submitted on September 4, 2003—over six years before the '318 Patent issued—the applicants explicitly notified the examiner about the copending '764 Application:

The Examiner's attention is directed to copending application number 10/362,764, naming Michel ARMAND et al. as inventor(s) and filed on June 19, 2003, and the documents cited therein, a copy of which is enclosed.

Ex. A ('318 Patent File History) at 4, 5 (requesting that the examiner "return a copy of this Information Disclosure Statement with the Examiner's initials adjacent to this paragraph indicating that this copending application has been considered"). Indeed, the '764 Application was also referenced by the '763 Application applicants in their Third Information Disclosure Statement, in which they further disclosed the documents that were cited in the '764 Application.

The documents cited herein were cited in copending Application No. 10/362,764, filed on June 19, 2003.

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Ex. A ('318 Patent File History) at 8 (Third Information Disclosure Statement filed February 21, 2006). A similar disclosure was also made in the '764 Application regarding the '763 Application:

The Examiner's attention is directed to copending application number 10/362,763, naming as inventor(s) Michel Armand et al., and filed on June 19, 2003, and the documents cited therein, a copy of which is enclosed.

See 37 C.F.R. § 1.54(b) ("Applicant will be informed of the application number and filing date by a filing receipt").

Ex. B ('260 Patent File History) at 3 (Second Information Disclosure Statement filed September 4, 2003).

The public record³ unequivocally controverts Plaintiffs' allegations that the patent applicants "did not disclose the existence of the copending patent applications and made a deliberate decision to withhold information relating to the copending patent applications." (Dkt. No. 1 ¶ 29). Such a demonstrably false allegation cannot "raise [Plaintiffs'] right to relief above the speculative level." *Twombly*, 550 U.S. at 555.

Similarly, the Complaint alleges: "On information and belief, . . . the **patent examiners may not have been aware of the copending patent applications** on related subject matter." (Dkt. No. 1 ¶ 29 (emphasis added)). However, like Plaintiffs' previous allegations regarding the applicants' disclosures to the USPTO, it is also demonstrably false that the examiner of the '763 Application was not aware of the copending '764 Application. For instance, the June 10, 2009 Examiner's Search Strategy and Results filing lists the '764 Application as the first search query conducted by the examiner:

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³ "It is well established that [courts] may properly take judicial notice of matters of public record," and "those [documents] attached to the motion to dismiss, so long as they are integral to the complaint and authentic." *Pennsylvania Higher Educ. Assistance Agency*, 745 F.3d at 136 (internal quotations and citations omitted); *see also Uniloc USA, Inc. v. ADP, LLC*, 772 F. App'x 890, 898 n.3 (Fed. Cir. 2019) ("The prosecution history is part of the intrinsic record of the patent and is a matter of public record," which "is thus subject to judicial notice") (internal quotation omitted); *Metacluster LT, UAB v. Bright Data Ltd.*, No. 2:22-CV-011-JRG-RSP, 2022 WL 18859434, at *1 (E.D. Tex. Dec. 20, 2022), *report and recommendation adopted*, No. 2:22-CV-0011-JRG-RSP, 2023 WL 416417 (E.D. Tex. Jan. 25, 2023) ("Communications before the Patent and Trademark Office that are matters of public record are subject to judicial notice and appropriate for this Court to consider at the pleading stage.").

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	3	10/362764	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/06/01 12:02

Ex. A ('318 Patent File History) at 11. The file history further reflects that the publication associated with the '764 Application was returned by a search conducted on July 3, 2007. *See* Ex. A ('318 Patent File History) at 10 (listing "20040086445 38" corresponding to U.S. Patent Pub. No. 2004/0086445A1). Contrary to Plaintiffs' allegations, the examiner was aware of the '764 Application during prosecution of the application leading to the '318 Patent.

Relatedly, the Complaint's allegation regarding materiality is also controverted by the public record:

On information and belief, the existence of the copending patent applications was material to patentability, because <u>had the patent examiners been aware of the copending patent applications</u>, they would have issued an obviousness-type <u>double patenting rejection and required the filing of a terminal disclaimer</u>, such that the '318 patent would have expired at the same time as the '260 patent' is also patently false.

(Dkt. No. 1 ¶ 30 (emphasis added)). Despite receiving multiple identifications of the copending '764 Application and even conducting a search related to that very application, the examiner subsequently issued the '318 Patent without issuing an OTDP rejection or requiring a terminal disclaimer. Ex. A ('318 Patent File History) at 13 (Issue Notification). Plaintiffs' allegation is simply not true.

Plaintiffs' literally false allegations cannot "raise [Plaintiffs'] right to relief above the speculative level" or otherwise preclude dismissal. *Twombly*, 550 U.S. at 555.

2. Plaintiffs' Claim for Inequitable Conduct Fails as Matter of Law

Striking only the literally false allegations just discussed from Plaintiffs' complaint, the remaining allegations in support of their claim for inequitable conduct read as follows:

- 28. On information and belief, the patent applicant and the attorneys and agents operating on their behalf in submitting the application leading to the '318 patent were aware of the filing of the patent application leading to the '260 patent, which application was filed on the same day. On information and belief, the patent applicant and the attorneys and agents operating on their behalf were aware of the substantial similarity of the subject matter described and claimed in the two patent applications throughout patent prosecution of the two patent families.
- 29. On information and belief, the patent applicants and the attorneys and agents operating on their behalf were aware that the two patent applications were before different patent examiners[.]
- 30. On information and belief, the existence of the copending patent applications was material to patentability[.] On information and belief-the patent applicants have obtained an improper time-wise extension of patent rights by obtaining a second patent (the '318 patent) having claims that are not patentably distinct from an earlier patent.

(Dkt. No. 1 ¶¶ 28-30 (removing only the demonstrably false facts discussed in § IV.A.1). Such an (attempted) bare recitation of the elements of inequitable conduct fails to meet Rule 9(b)'s pleading requirement. *See Exergen Corp.*, 575 F.3d at 1326–27 ("A pleading that simply avers the substantive elements of inequitable conduct, without setting forth the particularized factual bases for the allegation, does not satisfy Rule 9(b).").

Moreover, even considering Plaintiffs' false statements, Plaintiffs' allegations fail as a matter of law at least because: (i) no information was withheld from the USPTO, (ii) they fail to identify a specific individual alleged to have committed the inequitable conduct, (iii) they fail to plead the requisite but-for materiality of the allegedly withheld information, and (iv) they fail to plead the requisite specific intent to deceive the USPTO.

(i) No Information Was Withheld from the USPTO

As an initial matter, Plaintiffs fail to state a claim for inequitable conduct for a fundamental reason: **nothing was withheld from the USPTO**. The only information that Plaintiffs contend was withheld from the USPTO was "the existence of the copending patent applications." (Dkt. No. 1 ¶ 29, 30). However, as discussed above (*see supra* § IV.A.1), the copending patent applications were explicitly disclosed to the USPTO on **multiple occasions**. *See* Ex. A ('318 Patent File History) at 4, 8; Ex. B ('260 Patent File History) at 3. The Court need go no further than recognize this simple fact to dismiss the inequitable conduct allegations—a fact that Plaintiffs should themselves have recognized prior to filing their Complaint.

Indeed, Plaintiffs' Complaint is independently deficient because it relies solely "on information and belief," which is only "permitted under Rule 9(b) when essential information lies uniquely within another party's control," and even then "only if the pleading sets forth the specific facts upon which the belief is reasonably based." *Exergen Corp.*, 575 F.3d at 1330. Here, information like whether the copending applications were disclosed to the USPTO is not "uniquely within another party's control"—such information is readily discernible from a review of the public file histories.

(ii) Plaintiffs Failed to Plead a Specific Individual Who Committed the Alleged Acts

Plaintiffs further failed to plead their inequitable conduct claim with Rule 9(b)'s requisite particularly because they failed to identify "a **specific individual** [who] (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." *Exergen Corp.*, 575 F.3d at 1328–29 (emphasis added). Rather, Plaintiffs merely identified "the patent applicant and

the attorneys and agents operating on their behalf." (Dkt. No. ¶¶ 29-30). The Federal Circuit in *Exergen* made clear that exactly such pleading is legally insufficient under Rule 9(b):

First, the pleading refers generally to "Exergen, its agents and/or attorneys," Answer ¶¶ 40, 43, but fails to name the specific individual associated with the filing or prosecution of the application issuing as the '685 patent, who both knew of the material information and deliberately withheld or misrepresented it. The pleading thus fails to identify the "who" of the material omissions and misrepresentation.

Exergen Corp., 575 F.3d at 1329–30 (emphasis added) (stating that this deficiency is "fatal under Rule 9(b)"); see also Invista N. Am. S.a.r.l. v. M&G USA Corp., No. CV 11-1007-SLR-CJB, 2013 WL 12304544, at *7 (D. Del. May 3, 2013) ("This requirement is not satisfied by simply identifying individuals in a general averment, such as one that simply makes broad reference to all of the inventors and/or prosecuting attorneys."); Aevoe Corp. v. AE Tech. Co., Ltd., No. 2:12-cv-00053-GMN-NJK, 2013 WL 876036, at *6 (D. Nev. Mar. 7, 2013) (finding that defendant's inequitable conduct counterclaim failed to adequately identify the "who" where defendant's allegations referred only to "the Applicants" and thus failed to identify any specific individual that knew of material information and deliberately withheld or misrepresented it). Plaintiffs' "broadly cast net around the inventors and those acting on their behalf [] does not allow the court to reasonably infer that a specific individual both knew of the invalidating information and had a specific intent to deceive the PTO," and "[a]s such, the court [should] find[] that [Plaintiffs] ha[ve] insufficiently pled 'who' deceived the PTO." Senju Pharm. Co. v. Apotex, Inc., 921 F. Supp. 2d 297, 307 (D. Del. 2013).

(iii) Plaintiffs Fail to Plead But-For Materiality

Plaintiffs further fail to properly plead the materiality requirement. The Federal Circuit has clarified "that the materiality required to establish inequitable conduct is but-for materiality."

Therasense, 649 F.3d at 1291. In other words, "[w]hen an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art." *Therasense*, 649 F.3d at 1291.

Plaintiffs allege only the following regarding materiality:

On information and belief, the existence of the copending patent applications was material to patentability, because had the patent examiners been aware of the copending patent applications, they would have issued an obviousness-type double patenting rejection and required the filing of a terminal disclaimer.

(Dkt. No. 1 ¶ 30). Assuming *arguendo* that the applicants had failed to disclose the copending applications—which is clearly not the case—Plaintiffs further fail to plead the requisite but-for materiality because, as discussed above (*see supra* § IV.A.1), the PTO <u>was aware</u> of the copending application and allowed the claims of the '318 Patent nonetheless <u>after multiple</u>, <u>independent USPTO searches</u>. *See* Ex. A ('318 Patent File History) at 11 (June 10, 2009 Examiner's Search Strategy and Results listing the '764 Application for the first search conducted by the examiner), 10 (USPTO Patent Linguistics Utility System (PLUS) search listing "20040086445 38" corresponding to U.S. Patent Pub. No. 2004/0086445A1, which is the publication associated with the '764 Application). Plaintiffs cannot simply will patently false facts into existence by ignoring the public record, and such allegations cannot preclude dismissal.

(iv) Plaintiffs Fail to Plead Specific Intent to Deceive

The "specific intent" requirement is a high bar and "[a] finding that the misrepresentation or omission amounts to gross negligence or negligence under a 'should have known' standard does not satisfy this intent requirement." *Therasense*, 649 F.3d at 1290 (citing *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988)). The Federal Circuit has instructed that "a pleading of inequitable conduct under Rule 9(b) must include sufficient

allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." *Exergen Corp.*, 575 F.3d at 1328–29, n.5 ("A reasonable inference is one that is plausible and that flows logically from the facts alleged, including any objective indications of candor and good faith."). Plaintiffs' Complaint wholly fails to support a reasonable inference of a specific intent by any individual to deceive the PTO.

With respect to "specific intent," Plaintiffs' Complaint alleges only the following:

On information and belief, the patent applicants and the attorneys and agents operating on their behalf did not disclose the existence of the copending patent applications and <u>made a deliberate decision to withhold information relating to</u> the copending patent applications.

(Dkt. No. 1 ¶ 29 (emphasis added)). Setting aside the obvious—that the applicants, attorneys, and agents operating on their behalf could not have "made a deliberate decision to withhold information" that they did in fact disclose to the USPTO (*see supra* § IV.A.1)—Plaintiffs' allegations also fall woefully short of the pleading requirements of Rule 9(b).

Notably, Plaintiffs' allegations are premised solely "on information and belief," which "is permitted under Rule 9(b) . . ., but only if the pleading sets forth the specific facts upon which the belief is reasonably based." *Exergen Corp.*, 575 F.3d at 1330. Here, Plaintiffs provide no "specific facts" in support of their belief that "the patent applicant and the attorneys and agents operating on their behalf . . . made a <u>deliberate decision</u> to withhold information relating to the copending patent applications." (Dkt. No. 1 ¶ 29 (emphasis added)). As the Federal Circuit has noted, "[p]roving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive." *Therasense*, 649 F.3d at 1290; *see also Invista N. Am. S.a.r.l. v. M&G USA Corp.*, No. CV 11-1007-SLR-CJB, 2013

WL 12304544, at *11 (D. Del. May 3, 2013) ("[E]ven assuming materiality, [the party raising inequitable conduct] must offer some additional factual allegations regarding deceptive intent" to satisfy the pleading requirements of Rule 9(b).).

As "an inference of deceptive intent must be reasonable and drawn from a pleading's allegations of underlying fact to satisfy Rule 9(b)," the absence of any factual allegations in Plaintiffs' Complaint regarding a specific intent to deceive further mandates dismissal. See Exergen Corp., 575 F.3d at 1329 n.5, 1330–31 (holding that complaint which "pleaded [deceptive intent] solely on 'information and belief" and "provide[d] neither the 'information' on which it relie[d] nor any plausible reasons for its 'belief'" was properly dismissed as "deficient under Rule 9(b)"); Theta IP, LLC v. Samsung Elecs. Co. Ltd., No. WA:20-CV-00160-ADA, 2021 WL 2322936, at *2 (W.D. Tex. June 7, 2021) (dismissing an inequitable conduct counterclaim because the "only factual allegations to concern an 'intent to deceive' were based 'upon information and belief"); SynQor, Inc v. Artesyn Techs., Inc., No. 2:07-CV-497-TJW-CE, 2010 WL 3768093, at *8 (E.D. Tex. Sept. 9, 2010), report and recommendation adopted sub nom. SynQor, Inc. v. Artesyn Techs., Inc., No. 2:07-CV-497-TJW-CE, 2010 WL 3860154 (E.D. Tex. Sept. 28, 2010) ("Because Lineage and Cherokee's pleading sets forth no specific facts upon which their belief of Schlecht's intent to deceive the PTO is reasonably based, it fails to adequately plead intent to deceive under Rule 9(b).").

(v) Dismissal with Prejudice is Warranted

In sum, Plaintiffs' inequitable conduct allegations are premised on demonstrably false facts and fail as a matter of law at least because: (i) none of the information allegedly withheld from the USPTO was actually withheld, (ii) the Complaint fails to identify a specific individual alleged to have committed the inequitable conduct, (iii) the Complaint fails to plead the requisite but-for

materiality of the allegedly withheld information, and (iv) the Complaint fails to plead the requisite specific intent to deceive the USPTO. Each of these failures alone requires dismissal of Plaintiffs' inequitable conduct claim, but the combination warrants dismissal of Plaintiffs' claim with prejudice. Repleading cannot save such a baseless claim. Indeed, Plaintiffs have brought exactly the type of inequitable conduct claim that the Federal Circuit noted had "become an absolute plague" that was "cluttering up the patent system," and which it intended to preclude when it raised the requirements for such claims. *See Therasense*, 649 F.3d at 1291 (internal quotations omitted) (noting that the Federal Circuit specifically raised the standards for materiality and intent to "reduce the number of inequitable conduct cases before the courts"). As such, Defendants respectfully request that the Court dismiss Plaintiffs' inequitable conduct claim with prejudice.

B. Count I of the Complaint Should Be Dismissed Because the Allegations Fail to State a Claim for Patent Invalidity

Non-statutory obviousness-type double patenting is "a doctrine that limits the term of a patent or, at least, ties later-filed, commonly owned, obvious variations to the expiration date of <u>an</u> <u>earlier-filed reference patent</u>." *In re: Cellect, LLC*, 81 F.4th at 1226 (emphasis added), *cert. denied sub nom. Cellect, LLC v. Vidal*, No. 23-1231, 2024 WL 4426602 (U.S. Oct. 7, 2024). The Federal Circuit has instructed that patent claims "are entitled to their full term, <u>including the duly granted</u> <u>PTA</u>, unless they are found to be later-filed obvious variations of <u>earlier-filed</u>, <u>commonly owned</u> <u>claims</u>." *Id.* at 1230 (emphasis added).

As Judge Williams in the District of Delaware succinctly explained, "Ithat only earlier-filed patents are proper references is equitable, since the purpose of OTDP doctrine is to 'prevent a patent owner from extending his exclusive rights to an invention through claims in a later-filed patent that are not patentably distinct from claims in the earlier-filed patent." *Acadia Pharms. Inc.* v. *Aurobindo Pharma Ltd.*, 706 F. Supp. 3d 477, 487 (D. Del. 2023) (quoting *Procter & Gamble Co.*

v. Teva Pharms. USA, Inc., 566 F.3d 989, 999 (Fed. Cir. 2009)). By contrast, "[i]f a later-filed patent is used as a reference, the logic and purpose of OTDP is flipped on its head: rather than preventing a patent owner from unjustifiably extending the term of a patent, OTDP would operate to cut off a patent term that would have been valid but for a later-filed patent." Acadia Pharms., 706 F. Supp. 3d at 487.

Plaintiffs allege that "the patent owners have obtained an improper time-wise extension of patent rights by obtaining a second patent (the '318 [P]atent) having claims that are not patentably distinct from an earlier patent [(the '260 Patent)]," meaning "the claims of the '318 [P]atent are invalid." (Dkt. No. 1 ¶ 23). Defendants disagree that the claims of the two patents are patentably indistinct⁴, but an assessment of claim scope is unnecessary as the '260 Patent does not qualify as an OTDP reference under the Federal Circuit's precedent. *See Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367, 1375 n.4 (Fed. Cir. 2018) ("Because we find that the '565 patent is not a double patenting reference for the '229 patent, we need not address Ezra's arguments as to whether the '229 patent is patentably indistinct from the '565 patent.").

Here, Plaintiffs' purported reference patent, the '260 Patent, was <u>not</u> filed earlier than the '318 Patent—indeed, it was filed right after⁵ on the same day—and cannot be used as an OTDP reference patent for the '318 Patent. *See In re: Cellect, LLC*, 81 F.4th at 1230 ("[Patent claims] are entitled to their full term, including the duly granted PTA, unless they are found to be later-filed obvious variations of **earlier-filed, commonly owned claims.**"); *see also Acadia Pharms.*, 706 F.

⁴ Indeed, one needs to do little more than look at the chart of the claim terms that that Plaintiffs included in their Complaint to confirm that the claims are not "patentably indistinct." (Dkt. No. 1 ¶ 22).

⁵ As is indicated by the '318 Patent's lower application number (Application No. 10/362,**763**), it was in fact filed right before the '260 Patent's application (Application No. 10/362,**764**) on the same day.

Supp. 3d at 488 ("putative OTDP references <u>must be earlier-filed</u> to be available as a reference.") (emphasis added). Because the '260 Patent is not "earlier-filed" than the '318 Patent, Plaintiffs fail to state a claim for obviousness-type double patenting as a matter of law. *See Acadia Pharms.*, 706 F. Supp. 3d at 488 ("Because a patent must be earlier-filed to be available as an OTDP reference, the Court finds that the '271 patent does not qualify as a proper reference against the '740 patent.").

Indeed, the Federal Circuit in its precedential *Allergen* decision in August 2024 emphasized that an earlier-filed, later-expiring patent claim cannot be invalidated by a later-filed, earlier-expiring patent claim with the same priority date. *Allergan*, 111 F.4th at 1369 ("[A] first-filed, first-issued, later-expiring claim cannot be invalidated by a later-filed, later-issued, earlier-expiring reference claim having a common priority date."). As other courts have explained, "putative OTDP references must be earlier-filed to be available as a reference." *Acadia Pharms*, 706 F. Supp. 3d at 488.

It is undisputed that the patents share a common priority date claim of September 26, 2000. Ex. A ('318 Patent File History) at 1; Ex. B ('260 Patent File History) at 1. It is also undisputed that the patents were filed the same day on February 26, 2003, with the '318 Patent being filed first and the '260 Patent second. It is further undisputed that, by virtue of receiving a Patent Term Adjustment ("PTA") of 1,227 days due to USPTO delays, the '318 Patent claims have a later expiration date than the claims of the '260 Patent, which only received a PTA of 218 days.⁶

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⁶ But for the PTA awarded to the '318 Patent and the '260 Patent by statute due to USPTO delays, the patents would expire the same day and "obviousness-type double patenting [would] not apply as a matter of law." *See Zimmer Surgical, Inc. v. Stryker Corp.*, 365 F. Supp. 3d 466, 485 (D. Del. 2019). PTA extensions are calculated through a formula used by the PTO, as set forth in 35 U.S.C. § 154(b). It is not possible to predict ex ante the length of a PTA. That the '318 Patent now expires after the '260 Patent is a matter of pure happenstance. The reverse could easily have been made the case if the '318 Patent had fewer PTO delays during prosecution and been awarded a shorter PTA than the '260 Patent.

While the challenged patent in *Allergen* was also earlier-issued—which is not the case here as the '318 Patent issued later than the '260 Patent due to the USPTO delays—that fact does not change that dismissal is dictated by *Allergen*. The Federal Circuit in *Gilead* explained that for post-URAA⁷ patents, as here, issuance dates do not control in the OTDP analysis:

[I]f the double patenting inquiry was determined by issuance date for post-URAA patents, there could be a significant difference in an inventor's period of exclusivity over his invention (and its obvious variants) based on mere days' difference in the issuance of several patents to the inventor. Here, for example, if the '375 patent issued the day before the '483 patent, in Gilead's view, the last twenty-two months of the term of the '483 patent would be an improper extension of patent term.

Now if the '375 patent issued the day after the '483 patent, those last twenty-two months of the term of the '483 patent would not be an improper extension of patent term.

Such significant vacillations in an inventor's period of exclusivity over his invention and its obvious variants is simply too arbitrary, uncertain, and prone to gamesmanship. Congress could not have intended to inject the potential to disturb the consistent application of the doctrine of double patenting by passing the URAA.

Gilead Scis., Inc. v. Natco Pharma Ltd., 753 F.3d 1208, 1215–16 (Fed. Cir. 2014). In short, while "for double patenting inquiries, looking to patent issue dates had previously served as a reliable stand-in for the date that really mattered—patent expiration," for post-URAA patents "it is the comparison of [the] patent expiration dates that should control, not merely the issuance dates." Id. at 1214–15. In Gilead, "the patent owner had crafted a separate chain of applications, not tied to the priority date of an earlier-filed patent that claimed patentably indistinct subject matter" and thus sought to extend the 20-year patent term from filing. Allergan, 111 F.4th 1370 (citing Gilead, 753 F.3d at 1210). Under those circumstances, "between issuance date and expiration date, the latter

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⁷ See Allergan, 111 F.4th at 1367 ("Congress's passage of the Uruguay Round Agreements Act of 1994, Pub. L. No. 103-465, 108 Stat. 4809 ('URAA') changed how patent terms were determined. Instead of measuring from issuance date, a patent's term is now measured from its effective filing, or priority, date[.]").

serves as the better benchmark in determining the application of ODP post-URAA." *Id.* (citing *Gilead*, 753 F.3d at 1216). Given that the '318 Patent and the '260 Patent are both post-URAA patents, their issuance dates have no bearing on "the date that really matter[s]—patent expiration" and do not alter the fact that *Allergen* requires dismissal of Plaintiffs' claim. *Id.*

In the case of post-URAA patents, the main purpose of OTDP is to prevent patent owners from "claim[ing] different effective filing dates for different patents to extend the life of patent exclusivity." *Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355, 1367 (Fed. Cir. 2018) (citing *Gilead*, 753 F.3d at 1210–11 and *Abbvie Inc. v. Mathilda & Terence Kennedy Institute of Rheumatology Trust.*, 764 F.3d 1366, 1369–71 (Fed. Cir. 2014) as examples of such impermissible behavior); *see also Allergan*, 111 F.4th at 1371 ("*Abbvie* is a prime example of the post-URAA scenario we contemplated in *Gilead* where an inventor, seeking to prolong his exclusivity rights over his invention, applies for a second patent on an obvious variant of his invention protected by a first patent and achieves a later expiration date by choosing a different, later priority date than the one relied upon for the first patent.") (internal quotations omitted). This case presents no such concerns, as both the priority date and effective filing date for the '318 Patent and the '260 Patent are the same. *See* Ex. A ('318 Patent File History) at 1; Ex. B ('260 Patent File History) at 1. As the Federal Circuit stated in *Novartis AG*, and which is equally applicable here:

This case [] does not present the concerns that drove recent decisions of this court regarding obviousness-type double patenting in the post-URAA context. For example, there is no potential gamesmanship issue through structuring of priority claims as identified in *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014). . . . [T]here is also no concern that Novartis, once its '229 patent issued, sought to subsequently "secur[e] a second, later expiring patent for the same invention" as in *Abbvie Inc. v. Mathilda & Terence Kennedy Institute of Rheumatology Trust.*, 764 F.3d 1366, 1373 (Fed. Cir. 2014).

Novartis AG, 909 F.3d at 1374–75. Given the policy concerns that underlie OTDP to prevent gamesmanship based on priority dates, there is no reason to distinguish between the two patents at

issue here that were filed on the same day. To use the words of the Federal Circuit: "Put otherwise,

the fact that the ['318] patent expires later is of no consequence here because it is not a 'second, later

expiring patent for the same invention." Allergan, 111 F.4th at 1369 (emphasis in original) (quoting

Abbvie, 764 F.3d at 1373). Holding otherwise "would not only run afoul of the fundamental purposes

of ODP, but effectively abrogate the benefit Congress intended to bestow on patentees when

codifying PTA." *Allergan*, 111 F.4th at 1371.

At base, Plaintiffs have attempted to use a doctrine that "has limited force" for post-URAA

patents as a get-out-of-jail-free card for part of their license obligations. See In re Fallaux, 564

F.3d 1313, 1318 (Fed. Cir. 2009) (explaining that the "unjustified patent term extension

justification for obviousness-type double patenting has limited force" post-URAA). As with

Plaintiffs' inequitable conduct claim, their claim for invalidity based on obviousness-type double

patenting fails as a matter of law and should be dismissed with prejudice.

V. **CONCLUSION**

For the foregoing reasons, Defendants respectfully requests that the Court dismiss

Plaintiffs' Complaint with prejudice.

Dated: December 18, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on December 18, 2024, the foregoing was filed electronically and served on all counsel of record.

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